

Food and Drug Administration Rockville MD 20857

JAN -5 1994

Re: LAMISIL CREAM Docket No. 93E-0147

Charles E. Van Horn Patent Policy and Projects Administrator Office of the Assistant Commissioner for Patents U.S. Patent and Trademark Office Crystal Park Building 2, Suite 919 Washington, DC 20231

Dear Mr. Van Horn:

This is in regard to the patent term extension application, for U.S. Patent No. 4,755,534 filed by Sandoz, Ltd. under 35 U.S.C. § 156. The patent claims the human drug producto Lamisil Cream (terbinafine hydrochloride), NDA 20-192.

In the May 18, 1993 issue of the Federal Register (58 Fed. Reg. 28,984), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). notice provided that on or before November 15, 1993, 180 days after the publication of the determination, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and FDA has received no such petition. Therefore, FDA considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Director

Health Assessment Policy Staff

Office of Health Affairs

Robert S. Honor cc:

Patent and Trademark Affairs

Sandoz Pharmaceutical Corporation

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